

Attorney Docket No.: 5386.224-US
Application Serial No.: 10/083,058
Filed: February 25, 2002
Inventors: Havelund et al.

REMARKS

Claims 70-94 are pending in the present application. Added claims 70-94 find support in the original claims and in the specification at page 4, line 12 to page 5, line 8, at page 6, line 9 to page 8, line 22, and in the Examples shown on pages 10-16.

Rejections Of The Claims Under 35 U.S.C. 102

- A. Claims 61-69 are rejected under section 102(e) as anticipated by Havelund et al US Patent 6,011,007. In particular, the Examiner alleges that since Havelund "discloses the same composition as disclosed in the specification, with the same ionic strength and pH, the composition described in Havelund et al would inherently result in aggregate formations" (page 3 of Office Action).

Applicants respectfully traverse this rejection.

Havelund neither teaches nor suggests assaying preparations of insulin derivatives for their ability to form a water-soluble aggregate which has a size larger than aldolase (claims 70-94). Accordingly, withdrawal of this rejection is respectfully requested.

- B. Claims 61-69 are rejected as anticipated under section 102(e) as anticipated by Norup et al US Patent 5,866,538. The Examiner alleges that "the difference between the prior art and the instant application is that the reference does not specifically teach aggregation of the insulin" but that "since

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the reference discloses a composition with similar ionic strength and pH as the claimed composition, the composition disclosed by the reference would necessarily result in aggregate formations (page 3 of Office Action).

Applicants respectfully traverse this rejection.

Norup discloses preparations comprising human insulin or an analog or derivative thereof which also contain glycerol and/or mannitol and 5-100mM of a halogenide. As Norup neither teaches nor suggests the method of claims 70-94, withdrawal of this rejection is respectfully requested.

C. Claims 61-69 are rejected under section 102 (e) as anticipated by Havelund et al WO 95/07931. The Havelund PCT publication is a priority document in the 6,011,007 patent of Havelund cited above in A.

In reply, Applicants respectfully request withdrawal of this rejection for the reasons set forth above in A).


Accordingly, in view of the above amendments and remarks, Applicants respectfully submit that this application is in condition for allowance.

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The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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